REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of Claims

Claim 3 is requested to be cancelled without prejudice or disclaimer.

Claims 1-12 are currently being amended. Support for these amendments can be found throughout the specification as-filed, including the original claims. No new matter is being added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-12 are now pending.

II. Declaration

The examiner objects to the declaration as containing changes in the post office address of inventor that are not initialed. Accordingly, the examiner requires Applicants to file a new declaration.

Applicants will file a new declaration, as soon as one can be obtained from the inventor. Thus, Applicants respectfully request that the examiner acknowledge that the new declaration is acceptable in the next Office communication.

III. Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 1, 2, and 4-12 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. The examiner argues that "the specification, while being enabling for, a formulation comprising a hybridoma, said hybridoma comprising a DC and a tumor cell, does not reasonably provide enablement for, a formulation comprising a hybridoma, said hybridoma comprising a DC and a virally infected cell." Office action at 2. Applicants respectfully traverse this ground of rejection.

The specification provides sufficient guidance to both make and use the claimed invention without undue experimentation, as discussed below.

A. The Specification Teaches How To Make The Claimed Invention

The specification teaches that "the hybridomas ... of the present invention can be formed by any method known in the art" (page 8, lines 3-4). The specification goes on to provide one method of forming an APC-virally infected cell using polyethylene glycol (PEG) (page 8, lines 4-11). Moreover, the specification contains working examples demonstrating the formation of a hybridoma (page 11, lines 5-19). Thus, the specification provides guidance as to how to construct the claimed formulation.

The examiner contends that a hybridoma must be an immortal cell, and the examiner further argues that the specification does not describe how to make an immortal cell by fusing two mortal cells, a macrophage or a dendritic cell with a virally infected cell. As support for this contention, the examiner cites certain passages from literature references.

However, the specification does not require the hybridoma to be an immortal cell. Indeed, the specification defines a hybridoma as "a physical combination of at least two different cell types" (page 6, lines 14-15). The specification further specifies that the two different cells types can be "at least one APC and at least one virally infected cell" (page 6, lines 15-18). As noted above, the specification describes that fusion of cells was known in the art, and the

specification further describes one method of fusing cells employing PEG. Thus, the specification provides sufficient guidance to allow one of skill in the art to make the recited hybridoma without undue experimentation.

B. The Specification Teaches How To Use the Claimed Invention

The examiner contends that undue experimentation is required to practice the claimed invention, because "the formulations of the instant claims would be more likely to exacerbate viral infections than to treat or prevent them." Office action at 4. As support for this contention, the examiner cites two references relating to HIV. *See* Frank, CURRENT MOL. MEDICINE 2:229 (2002); Cohen, SCIENCE 295:1616 (2002).

Contrary to the examiner's assertions, one of skill in the art would be able to use the claimed formulations and compositions without undue experimentation. Indeed, Marañón *et al.*, PNAS 101(16):6092:97 (2004) demonstrates that the claimed invention can be used without undue experimentation. Specifically, Marañón studied the presentation of HIV antigens from dendritic cells and concluded that dendritic cells that present viral antigens stimulate virus-specific CD8+ cells. In fact, Marañón concluded that dendritic cell antigen presentation could be "exploited to eradicate latently infected reservoirs" (Marañón, abstract, emphasis added). Thus, Marañón demonstrates that the claimed invention could be employed in the treatment of HIV infection.

Applicants note that the claims are directed to formulations and compositions rather than methods of treating all viral infection. Thus, Applicants need not demonstrate that the claimed invention can be used to treat all viral infections, but instead, enablement requires only that the claimed invention can be employed in some use by one of skill in the art without undue experimentation.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Claim Rejections — 35 U.S.C. § 102

Claims 1 to 3 stand rejected as allegedly being anticipated by Peters, JH, IMMUNOBIOLOGY 7(21):159 (1981) ("Peters"). The Examiner argues that "Peters teaches a formulation comprising a hybridoma having a first DC (from spleen) fused to a sarcoma cell (see entire document) capable of inducing effective CTL immunity." Office Action, page 5, paragraph 7.

While not acquiescing in the propriety of the rejection, Applicants have amended the claims to omit the term "a tumor cell." Thus, the claims are now directed to formulations and pharmaceutical compositions comprising a hybridoma having an "antigen presenting cell selected from the group consisting of a macrophage and a dendritic cell" fused to "a virally infected cell." Accordingly, this amendment renders the rejection moot.

V. Claim Rejections — 35 U.S.C. § 103

A. Rejection Based on Guo in view of Sornasse

Claims 1, 2 and 5 to 12 stand rejected as allegedly being unpatentable over Guo *et al.*, SCIENCE 263:518-520 (1994) ("Guo") in view of Sornasse *et al.*, J. EXP. MED. 175:15-21 (1992). Office Action, page 6, paragraph 9. The Examiner argues that Guo teaches a hybridoma "comprising an antigen-presenting B cell and a carcinoma cell," which "induce[s] a protective anti-tumor immune response." Office action at 6. The Examiner agrees that Guo "does not teach the use of a DC as the antigen presenting component of the hybrid" and relies on Sornasse to remedy Guo's deficiency. *Id.*

For the reasons noted above in Section IV, the foregoing amendment to the claims renders this rejection moot.

B. Rejection Based on Guo in view of Sornasse in further view of The Merck Manual 1992

As discussed above in Section IV, the foregoing amendment to the claims renders this rejection moot.

IV. Claim Rejections — Double Patenting

A. 35 U.S.C. § 101

Claims 1 to 12 stand provisionally rejected as allegedly claiming the same invention as that of claims 1 to 12 of copending Application No. 11/089,025 (Atty. Dkt. No. 076333-0366).

Applicants respectfully request that any action in response to this rejection be deferred until allowable subject matter is identified in this application.

B. Judicially Created Doctrine of Obviousness-type Double Patenting

Claims 1-3 and 5-12 stand provisionally rejected as allegedly being unpatentable over claims 1-3 and 5-12 of copending Application No. 09/208,549 (Atty. Dkt. No. 076333-0242). The Examiner argues that "the claims of the '549 application recite a formulation and pharmaceutical composition comprising a hybridoma having an antigen presenting cell fused to a tumor cell." For the reasons discussed above in Section IV, the foregoing amendment to the claims renders this rejection moot.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 7 November 2005

By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicants
Registration No. 29,768